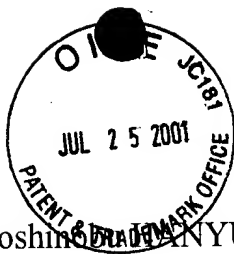


P20757.A02



#67/31/01
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JUL 27 2001

Applicant : Yoshino et al.

Group Art Unit: 1632

Serial No. : 09/810,483

Examiner: Arun Chakrabarti, Ph.D

Filed : March 19, 2001

For : POWDER CONTAINING PHYSIOLOGICALLY ACTIVE PEPTIDE

ELECTION WITH TRAVERSE

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This paper is responsive to the Requirement for Restriction mailed from the Patent and Trademark Office June 25, 2001, in the above application and setting a thirty-day period for response thereto which runs through July 25, 2001. Inasmuch as this response is being filed within the thirty-day period for response, it is believed that no extension of time is required. However, if an extension of time is deemed by the Patent and Trademark Office to be necessary, the same is hereby requested and the Patent and Trademark Office is authorized to charge any extension of time fees and any other fees necessary for maintaining the pendency of this application to deposit account No. 19-0089.

Summary of Restriction Requirement

The Restriction Requirement states that the Examiner has determined that two distinct inventions are contained in this application, namely:

- I) Claims 1 - 24, drawn to a method of making dried protein, classified in class 34, subclass 282+; and
- II) Claims 25-32, drawn to a composition of peptides, classified in class 530, subclass 300+.

The Examiner has therefore required that an election be made between these inventions.

Election

In response to the Restriction Requirement, Applicants elect the invention of Group II (Claims 25-32), with traverse.

Traverse

Applicants submit that a restriction is inappropriate in this case and should be withdrawn.

Initially, it should be pointed out that the requirement for restriction omits one of the two criteria of a proper requirement as now established by U.S. Patent and Trademark Office policy, as set forth in MPEP 803 (Revision 2, July 1996), viz. that "an appropriate explanation" must be advanced by the Examiner as to the existence of a "serious burden" if a restriction were not required. Due to the aforementioned omission, it is respectfully submitted that the requirement for restriction is improper and, consequently, its withdrawal

is respectfully requested.

The restriction should also be withdrawn because there is no serious search burden. In MPEP Chapter 800, the Office sets forth its policy by which Examiners are guided in requiring restriction under 35 U.S.C. §121. Section 803 states that “[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” MPEP § 803 [R-2], page 800-3 (Rev. 2, July 1996).

Although Groups I and II differ in that Group I is directed to a method of making dried proteins and materials and Group II is directed to compositions of peptides, the underlying concepts are quite similar. A search for methods of making dried proteins should cover areas relevant to compositions of peptides formed by these methods. In other words, if a search area were relevant to the method of making a dried protein, it would also be relevant to compositions of peptides formed by the method. Therefore, as a practical matter, the searches for the two groups appear to significantly overlap, if not actually be co-extensive. Thus, the search burden would not appear to be serious.

Furthermore, as the Examiner appreciates, in order to justify a requirement for restriction, the difference between the invention defined by the various groups of the claims must be material. Despite this requirement, the Examiner has not stated or offered a definition of what is “materially different” to justify a requirement for restriction, or offered

an explanation as to why the mentioned differences are material for restriction requirement purposes.

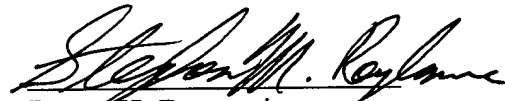
Absent a definition or explanation of this concept, it is respectfully submitted that the Examiner has not explained how such a difference is “materially different” so as to justify restriction between the Groups. In this regard, the Examiner has merely stated that the two Groups are materially different, and thereby concluded that the inventions are distinct. However, the Examiner does not indicate how the difference between the two groups is a material difference to support a requirement for restriction, especially when the search areas for the two groups of invention would significantly overlap.

It is also important for the Examiner to understand that Applicants have paid a filing fee for an examination of all the claims in this application. It is respectfully submitted that such an examination in full is part of the *quid pro quo* for which Applicants have the paid the fees for all of the claims under examination. If, however, the Examiner refuses to examine all the claims paid for when filing this application and persists in requiring Applicant to file a divisional application to allow prosecution of both groups of claims, the Examiner is essentially forcing Applicant to pay duplicative fees for the non-elected or withdrawn claims. In view of the foregoing, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn, in view of the lack of a serious burden and the lack of material differences for examination purposes between the Groups.

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If the Examiner has any questions, or wishes to discuss this matter, the Examiner is respectfully invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
Yoshinobu HANYU et al.


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Reg. No. 29,027 *Reg No. 31,296*

July 24, 2001
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